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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,791	07/18/2007	Robert Charles Rees	42133-200861	9495
23643 7590 12/12/2007 BARNES & THORNBURG LLP 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204			EXAMINER DUFFY, BRADLEY	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,791	Applicant(s) REES ET AL.	
	Examiner Brad Duffy	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 and 13-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Notice to comply</u> . |

DETAILED ACTION

1. The preliminary amendment filed September 29, 2006 is acknowledged and has been entered. Claims 1-10 and 13-27 have been amended. Claims 11-12 have been canceled. Claims 28-31 have been newly added.
2. Claims 1-10 and 13-31 are pending in this application and are currently subject to restriction.

Lack of Compliance with the Sequence Rules

Drawings

3. The drawings set forth as Figures 1 is objected to because the figure depicts an amino acid sequence, which is not identified by sequence identification number, either in the figure or in the brief description of figures at page 12. Sequences appearing in the specification and/or drawings must be identified by a sequence identifier in accordance with 37 C.F.R. 1.821(d); sequence identifiers for sequences appearing in the drawings may appear in the drawings or in the brief description of the drawings.

A replacement drawing sheet, including the correction, is required, if the drawings are objected to. See 37 CFR 1.121(d). However, this ground of objection would be withdrawn, so that a replacement drawing would not be required, if Applicant were to amend the brief description of the figure at pages 8 and 10 of the specification to include sequence identification numbers.

Specification

4. The disclosure is objected to for the following reason: The specification contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). Sequences appearing in the specification and/or drawings must be identified by sequence identifier

in accordance with 37 C.F.R. 1.821(d). According to 37 CFR § 1.821(a), an unbranched sequence of four or more specifically identified amino acids or an unbranched sequence of ten or more nucleotides must be identified by sequence identification numbers. See MPEP § 2422.01.

In this instance, the sequence depicted in Figure 1 is not identified by sequence identification number, either in the figure or in the brief description of figure at page 12. Additionally, page 7, line 30 of the specification discloses the amino acid sequence "MYIGEMLR" without a SEQ ID NO and it appears that this sequence is not listed in the present Sequence Listing.

Applicant must provide appropriate amendments to the specification or drawings inserting the required sequence identifiers. Sequence identifiers for sequences appearing in the drawings may appear in the drawings or in the brief description of the drawings.

As noted in the attached Notice to Comply, appropriate action correcting this deficiency is required. If necessary to correct the deficiency, Applicant must submit paper and computer-readable copies of a substitute sequence listing, together with an amendment directing its entry into the specification and a statement that the content of both copies are the same and, where applicable, include no new matter.

Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be further examined under 35 U.S.C. §§ 131 and 132.

Election/Restrictions

5. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to

elect a single invention to which the claims must be restricted.

Group I, claims 1-6, 19, 25, 26 and 30, drawn to isolated nucleic acid molecules encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code and vectors, host cells, kits, vaccines or immunogenic compositions comprising said nucleic acid molecules.

Group II, claims 7-9, 27, 28 and 31, drawn to isolated proteins comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code, derivatives or fragments of said proteins and kits and immunogenic compositions comprising said proteins.

Group III, claims 10 and 29, drawn to monoclonal antibodies capable of specifically binding to proteins comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid

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molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code, monoclonal antibodies capable of specifically binding derivatives or fragments of said proteins and a kit comprising a said antibodies.

Group IV, claims 15-17, insofar as they are drawn to a method of detecting cancer in a patient comprising the step of detecting elevated levels of a protein comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code.

Group V, claims 15-17, insofar as they are drawn to a method of monitoring cancer in a patient comprising the step of monitoring elevated levels of a protein comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code.

Group VI, claim 18, insofar it is drawn to a method of detecting gastro-intestinal cancer in a patient comprising the step of detecting elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising

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the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

Group VII, claim 18, insofar it is drawn to a method of detecting kidney cancer in a patient comprising the step of detecting elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

Group VIII, claim 18, insofar it is drawn to a method of detecting prostate cancer in a patient comprising the step of detecting elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

Group IX, claim 18, insofar it is drawn to a method of monitoring gastro-intestinal cancer in a patient comprising the step of monitoring elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules

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comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

Group X, claim 18, insofar it is drawn to a method of monitoring kidney cancer in a patient comprising the step of monitoring elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

Group XI, claim 18, insofar it is drawn to a method of monitoring prostate cancer in a patient comprising the step of monitoring elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

Group XII, claims 20-21 and 24, drawn to a method of prophylaxis or treatment of cancer comprising the step of administering to a patient a pharmaceutically effective amount of a nucleic acid molecule comprising nucleic acid molecules encoding T128

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polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code.

Group XIII, claim 22, drawn to a method of prophylaxis or treatment of cancer comprising the step of administering to a patient a pharmaceutically effective amount of a protein comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code.

Group XIV, claims 23, drawn to a method of prophylaxis or treatment of cancer comprising the step of administering to a patient a pharmaceutically effective amount of monoclonal antibodies capable of specifically binding to proteins comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code or monoclonal antibodies capable of specifically binding derivatives or fragments of said proteins.

6. Claims 13-14 are linking claims, linking the inventions of Groups VI-VII or, strictly

in the alternative, Groups IX-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01

7. The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

To have a general inventive concept under PCT Rule 13.1, the inventions need to be linked by a special technical feature. The technical feature of claim 1 is nucleic acid molecules encoding SEQ ID NO:1, polypeptides at least 80% identical to SEQ ID NO:1 or a fragment thereof or nucleic acid molecules that specifically hybridize with a nucleic acid molecule encoding SEQ ID NO:1. This claim lacks inventive step over Lisziewicz et al (PNAS, 89:11209-11213, 1992). Lisziewicz et al teach degenerate nucleic acid molecules that are 28 base pairs in length that comprise any DNA nucleotide at each position (i.e., at each position the nucleic acid can comprise A, T, G or C) (see entire document, e.g., page 11209, right column). Since these nucleic acids are degenerate, Lisziewicz et al teach nucleic acids that specifically hybridize with a nucleic acid molecule encoding SEQ ID NO:1. Since Lisziewicz et al teach the technical feature recited in claim 1, it is not a special technical feature and the groups do not relate to a single general inventive concept as required under PCT Rule 13.1.

For these reasons, the special technical feature of the invention of Group I is isolated nucleic acid molecules encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code.

The special technical feature of the invention of Group II is isolated proteins comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code, derivatives or fragments of said proteins.

The special technical feature of the invention of Group III is monoclonal antibodies capable of specifically binding to proteins comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code, monoclonal antibodies capable of specifically binding derivatives or fragments of said proteins and a kit comprising a said antibodies.

The special technical feature of the invention of Group IV is detecting cancer in a patient comprising the step of detecting elevated levels of a protein comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues

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642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code.

The special technical feature of the invention of Group V is monitoring cancer in a patient comprising the step of monitoring elevated levels of a protein comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code.

The special technical feature of the invention of Group VI is detecting gastrointestinal cancer in a patient comprising the step of detecting elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

The special technical feature of the invention of Group VII is detecting kidney cancer in a patient comprising the step of detecting elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

The special technical feature of the invention of Group VIII is detecting prostate

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cancer in a patient comprising the step of detecting elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

The special technical feature of the invention of Group IX is monitoring gastrointestinal cancer in a patient comprising the step of monitoring elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

The special technical feature of the invention of Group X is monitoring kidney cancer in a patient comprising the step of monitoring elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

The special technical feature of the invention of Group XI is monitoring prostate cancer in a patient comprising the step of monitoring elevated levels of a nucleic acid molecule encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the

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nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code in a sample from a patient.

The special technical feature of the invention of Group XII is preventing or treating cancer comprising the step of administering to a patient a pharmaceutically effective amount of a nucleic acid molecule comprising nucleic acid molecules encoding T128 polypeptide (SEQ ID NO: 1), a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code.

The special technical feature of the invention of Group XIII is preventing or treating cancer comprising the step of administering to a patient a pharmaceutically effective amount of a protein comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code.

The special technical feature of the invention of Group XIV is preventing or treating cancer comprising the step of administering to a patient a pharmaceutically effective amount of monoclonal antibodies capable of specifically binding to proteins comprising an amino acid sequence encoded by a nucleic acid that encode SEQ ID NO: 1, a polypeptide at least 80% identical to SEQ ID NO:1, or a fragment thereof, nucleic acid molecules comprising the nucleotide sequence depicted between nucleic acid residues 642 and 1688 of SEQ ID NO: 2, nucleic acid molecules which specifically

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hybridizes to said nucleic acid molecules, nucleic acid molecules the sequence of which differs from the sequence of said nucleic acid molecules due to the degeneracy of the genetic code or monoclonal antibodies capable of specifically binding derivatives or fragments of said proteins.

Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

8. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.** The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

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include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935
bd
December 6, 2007

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner, Art Unit 1643

Notice to Comply	Application No. 10/594,791	Applicant(s) REES ET AL.	
	Examiner Brad Duffy	Art Unit 1643	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e). The correct SEQ ID NO:2 is present in the paper copy of the of the sequence listing only. Therefore a search of the correct sequence is not possible.
- ☒ 7. Other: The sequence depicted in Figure 1 is not identified by sequence identification number. Additionally, page 7, line 30 of the specification discloses the amino acid sequence "MYIGEMLR" and it appears that this sequence is not in the current listing.

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923

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